The Innovative Medicines Initiative: an engine for therapeutic innovation

Michel Goldman
26.11.2014 • Brussels • Bringing health-related life science and technology sectors into IMI2
The pillars of innovation

- Scientific excellence
- Market access
- Patient access
- Rewarding systems
IMI – Europe’s partnership for health

> €5 bn

€2.5 bn

Partnership 2008 - 2024

€2.5 bn
IMI – key concepts

- Focus on unmet needs
- Non-competitive collaborative research
- Open innovation
  - Data sharing,
  - Dissemination of results...
IMI: a community without borders

- 650 academic teams
- 120 SMEs
- 25 patient orgs
- 409 EFPIA teams
- 17 regulators
- Over 6,000 researchers
- 59 public-private consortia
IMI’s flexible intellectual property policy

Support to industry

Incentive to participate

Dissemination of information

Flexibility

+ trusted party

Freedom of access

Compensation for IP
A typical IMI consortium

- **EFPIA**
  - Pharma 1
  - Pharma 2
  - Pharma 3
  - Pharma 4
  - Pharma 5
  - Pharma 6

- **Academia**
- **Small and medium-sized enterprises**
- **Patients’ organisations**
- **Hospitals**
- **Regulators**
IMI 1 – € 2 bn budget breakdown

- Diabetes
- Drug safety
- Brain disorders
- Drug discovery
- Infectious diseases
- Antibiotics
- Vaccines
- Lung diseases
- Inflammatory disorders
- Geriatrics
- Drug delivery
- Sustainable chemistry
- Relative effectiveness
- Education & Training
Scientific output of IMI projects

Thomson Reuters, 2014

Citation impact

Percentage of highly cited papers

World average
TI Pharma
Wellcome Trust
FNIH
IMI
Antimicrobial resistance – a growing threat

- 25 000 Europeans killed / year
- €1.5 bn costs to economy / year
- 2 new classes of antibiotics in the last 30 years
IMI already invested €655 million for:

- Solving **scientific challenges**
- Fostering **new models of industrial collaborations**
- Developing **clinical networks**
- Revisiting **regulatory rules**
- Providing **incentives to industry**
IMI’s drug discovery platforms

European Lead Factory Focus: identification of new hits

‘Qualified’ hit

European Lead Factory

ELF Budget:
- €92 m EFPIA in-kind
- €80 m IMI JU

European Lead Factory Focus:
- Target
- screening
- Hit-to-lead
- Lead-to-candidate
- Preclinical
- Phase I
- Phase II
- Phase III

ND4BB Drug Discovery Platform

ENABLE Budget:
- €26 m EFPIA in-kind
- €58 m IMI JU

ENABLE focus: to move promising hits into early clinical development

ENABLE focus: to move promising hits into early clinical development

europeanleadfactory.eu

nd4bb-enable.eu
Schizophrenia: the power of shared data

- 5 companies (AstraZeneca, J&J, Eli Lilly, Lüdbeck, Pfizer)
- 34 clinical trials testing second generation anti-psychotics
- 11,670 patients

Drug-placebo differences already significant:
- after 4 vs. 6 wks observation
- with 40% less patients

when appropriate gender balance, symptoms and disease duration are selected

Rabinowitz J et al., J Clin Psychiat 2014, in press
Alzheimer’s disease: an urgent need for new therapeutic strategies

<table>
<thead>
<tr>
<th>Major public health need</th>
<th>Recent failures</th>
<th>Hurdles to drug development</th>
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<tr>
<td>- 10m Europeans affected, will reach 14m by 2040</td>
<td>Inconclusive results of phase 3 clinical trials:</td>
<td>- Complexity of brain pathology</td>
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<tr>
<td>- Annual cost in EU: €180b, will reach 250b by 2030</td>
<td>- solanezumab</td>
<td>- Patients’ heterogeneity</td>
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<td></td>
<td>- bapineuzumab</td>
<td>- Lack of validated markers</td>
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<td>- human immunoglobulins</td>
<td>- for disease activity</td>
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How IMI addresses Alzheimer’s disease

IMI invests €167 million in 4 projects aiming at:

- Developing models to predict the efficacy of drug candidates
- Connecting data on 40 millions of individuals to decipher links between genetic background, biological abnormalities, brain imaging changes, mental symptoms and disease progression
- Identifying subgroups of the disease allowing to tailor therapies according to the different causal factors involved
- Implementing adaptive trial designs
Neuronal alterations in autism models are reversible

Re-expression of Nlgn3 in adolescent mice restores normal mGluR1 protein levels and results in removal of ectopic synapses.
Two largest clinical trials for early detection and monitoring of ASD children

**Identification of biomarkers that precede ASD onset**
- Prospective study of 300 high-risk infants (3 and 7 months) with older siblings with ASD, and 100 low-risk
- Infant cognition, behavior, neuroimaging, neurophysiology
- Relation to symptoms/diagnosis of ASD at outcome

**Accelerated longitudinal study for validation of ASD biomarkers in children and adults**
- 450 ASD patients and 300 controls
- Magnetic resonance imaging, event-related potential, eye-tracking
A genetically engineered human pancreatic β cell line exhibiting glucose-inducible insulin secretion

Philippe Ravassard,1,2,3 Yasmine Hachouz,2,4 Séverine Pechberty,4,5 Emilie Bricout-Neveu,2,4 Mathieu Armanet,5,7 Paul Czemichow,4 and Raphael Scharffmann2

1Université Pierre et Marie Curie-Paris 6, Biotechnology and Biotherapy Team, Centre de Recherche de l’Institut du Cerveau et de la Moelle épinière (CRiCM), UMR S 975, Paris, France. 2Inserm, UJM S 7225, Paris, France. 3Inserm, U1358, Paris, France. 4Endocrin, Paris, France. 5Inserm U1045, Research Center Growth and Signalling, Université Paris Descartes, Sorbonne Paris Cité, Faculté de Médecine, Hôpital Bichat, Paris, France. 6Cell Therapy Unit, Hôpital Saint Louis, APHP, and University Paris 7, Paris, France. 7Inserm U1072, Centre de Recherches des Cordeliers, Paris, France.
Novel predictive systems for drug toxicity

- 13 EFPIA companies
- 12 Public organisations
- 5 SMEs
- Total Budget: 13.9 Mi €

A Multiscale Simulation System for the Prediction of Drug-Induced Cardiotoxicity

Advancing benefit-risk assessment of medicines

Case study: Natalizumab

- Relapse
- Progression
- Inconvenience
- Herpes infections
- PML
- Congenital defects
- Liver changes
- Seizures
- Injection reactions
- Hypersensitivity
- Flu-like symptoms

TOTAL

Benefit-risk index
IMI 2: What’s new?

- Projects developed by other industries active in healthcare (ICT, Imaging, Medical Devices....)
- Greater focus on benefits for patients and society
- **Simplified** funding rates & reporting (aligned with H2020)
- **More types of organisations** eligible for funding (charities)
A single set of rules

- Covering all H2020 research and innovation actions
- Adaptability where needed:
  - Entities eligible for funding
  - IP

etc.
The measures of success

- New models developed & published
- Setting new standards
- In house implementation by industry
- Impact on regulatory guidelines

Better Science = Better Decisions
Thank you

Michel Goldman • Executive Director
michel.goldman@imi.europa.eu

www.imi.europa.eu
@IMI_JU